§170.315(b)(6) Data export

2015 Edition CCGs

Version 1.5 Updated on 06-15-2020

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-29-2015
1.1	Updated to reflect refined language included in corrections notice issued on December 11, 2015. Clarifications added around date range requirement, and cognitive status observation. Typographical errors removed.	02-08-2016
1.2	Provides notification of March 2017 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(6)(ii).	09-29-2017
1.3	Provides notification of April 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(6)(ii). Note: Due to an error in calculation ONC is also updating the dates for compliance with the March 2017 Validator Update of C-CDA 2.1 Corrections that	05-02-2018

	were adopted September 29, 2017.	
1.4	Provides notification of August 2018 Validator Update of C-CDA 2.1 Corrections adoption and compliance requirements within paragraph (b)(6)(ii).	09-21-2018
1.5	Added clarification for time-limited certification to this criterion per the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule.	06-15-2020

Regulation Text

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§170.315(b)(6) *Data export*—

(i) *General requirements for export summary configuration.*

(A) Enable a user to set the configuration options specified in paragraphs (b)(6)(iii) and (iv) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

(B) Limit the ability of users who can create export summaries in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(ii) *Creation.* Enable a user to create export summaries formatted in accordance with the standard specified in §170.205(a)(4) using the Continuity of Care Document document template that includes, at a minimum:

(A) The Common Clinical Data Set.

(B) *Encounter diagnoses.* Formatted according to at least one of the following standards:

(1) The standard specified in §170.207(i).

(2) At a minimum, the version of the standard specified in §170.207(a)(4).

(C) Cognitive status.

(D) Functional status.

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only.* Discharge instructions.

(iii) *Timeframe configuration.*

(A) Enable a user to set the date and time period within which data would be used to create the export summaries. This must include the ability to enter in a start and end date and time range.

(B) Consistent with the date and time period specified in paragraph (b)(6)(iii)(A) of this section, enable a user to do each of the following:

(1) Create export summaries in real-time;
(2) Create export summaries based on a relative date and time (e.g., the first of every month at 1:00 a.m.); and
(3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00 a.m.).

(iv) *Location configuration.* Enable a user to set the storage location to which the export summary or export summaries are intended to be saved.

Standard(s) Referenced

Paragraph (b)(6)(ii)

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use Release 2.1, August 2015

§ 170.207(a)(4) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release

§ 170.207(i) ICD-10-CM

Please refer to the Data Elements and Vocabularies applicable to the Common Clinical Data Set (CCDS) as outlined in the Common Clinical Data Set Reference Document

Certification Companion Guide: Data export

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble
Link to Correction Notice Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Revised	No	Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(b)(6). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(b) "paragraph (b)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (b) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be tested once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
  - Integrity (§ 170.315(d)(8))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility-centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.
- C-CDA creation performance (§ 170.315(g)(6)) does not need to be explicitly tested with this criterion unless it is the only criterion within the scope of the requested certification that includes C-CDA creation capabilities. Note that the application of § 170.315(g)(6) depends on the C-CDA templates explicitly required by the C-CDA-referenced criterion or criteria included within the scope of the certificate sought. Please refer to the C-CDA creation performance Certification Companion Guide for more details.

Table for Design and Performance

- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))
- Consolidated CDA creation performance (§ 170.315(g)(6))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- § 170.314(b)(7) “data portability” is now named § 170.315(b)(6) “data export”. To provide additional clarity of the criterion concept, we have decided to name the adopted certification criterion “data export”. [see also 80 FR 62645]
- This criterion will be removed from 2015 Edition Base EHR definition effective July 2, 2020. [see also 80 FR 25671]
- § 170.315(b)(10) “EHI export” will replace § 170.315(b)(6) “data export”. ONC–ACBs will be permitted to issue certificates for § 170.315(b)(6) until May 1, 2023 during the transition period to § 170.315(b)(10). We have included a provision in § 170.550(m)(2) to only allow ONC-ACBs to issue certificates for this criterion until May 1, 2023. [see also 80 FR 25720]
- Health IT developers with health IT certified to the prior certification criterion in § 170.315(b)(6) do not have to update such certified health IT to the Cures update revisions, but are permitted to maintain or seek new Health IT Module certification to this criterion should they desire this functionality. [see also 80 FR 25671]

Paragraph (b)(6)(i)(A)

Technical outcome – A user can set configuration options for data elements, date and time ranges, and locations as specified in paragraphs (b)(6)(ii) through (iv) of this section when creating an export summary as well as a set of export summaries for patients whose information is stored in the technology.

Clarifications:

- We expect that Health IT must be able to send all required data for a specific date range specified, but we acknowledge that there will be organizational policies / safety best practices that will dictate when records qualify on readiness, and we expect that vendors will employ user-centered design and return information in a way that prioritizes patient preferences and usability.

Paragraph (b)(6)(i)(B)

Technical outcome – The technology limits users who can create export summaries in at least one of two ways:

(1) To a specific set of identified users.
(2) As a system administrative function.

Clarification:

- This provision that “limits” functionality on the type of users that may execute the data export functionality is intended to be used by and at the discretion of the provider organization implementing the technology. In other words, this functionality cannot be used by health IT developers as an implicit way to thwart or moot the overarching user-driven aspect of this certification criterion. [see also 80 FR 62646]

Paragraph (b)(6)(ii)

Technical outcome – A user can configure the technology to create export summaries using the Continuity of Care Document document template (from the Consolidated CDA Release 2.1) that includes the data specified in (ii)(A)-(F), as applicable for the setting.

Clarifications:

- To demonstrate compliance with this certification criterion, EHR technology must "enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to" the C-CDA standard (77 FR 54193). [see also FAQ #49] For the 2015 Edition, the user must be able to choose to create export summaries for one patient, a set of patients, or all patients ("for as many patients selected"). If the user chooses to create export summaries for a set of patients or all patients, this functionality cannot be satisfied by a user individually creating an export summary for each patient one-by-one. [see also 77 FR 54193]
- This certification criterion's purpose is to enable a user to export clinical data from health IT for one patient, a set of patients, or a subset of that set of patients. The functionality included in the criterion is intended to support a range of uses determined by a user and it was not our intention to prescribe or imply particular uses for this functionality. We also note that this functionality is not intended to and may not be sufficient to accomplish a full migration from one product to another without additional intervention because of the scope of this criterion. Specifically, the data and document templates specified in this criterion would not likely support a full migration, which could include administrative data such as billing information. The criterion's functionality could, however, support the migration of clinical data between health IT systems and can play a role in expediting such an activity if so determined by the user. [see 80 FR 62645]
- Consistent with other responses provided in this final rule, this certification criterion requires conformance to the C-CDA R2.1. In consideration of comments received on the Proposed Rule, we have limited the C-CDA document template scope for this criterion to the CCD document template. We note that the vocabularies used by the C-CDA R2.1 are defined through the Standards Developing Organization (SDO) process and we do not seek to change that approach via this rulemaking (i.e., we adopt the C-CDA R2.1 as published). We note that we have adopted this criterion with the proposed inclusion of the Common Clinical Data Set and other specified data. [see 80 FR 62645]
- Substitution of test data codes for valid alternative codes is acceptable provided they are valid, appropriate, and meet the 2015 Edition certification criteria requirements.
  - Procedures and lab tests are both required to be coded with respective standards. "Lab tests", if referred to as "future scheduled tests" needed to be coded. The HL7 C-CDA companion guide suggests that future scheduled tests belong in the Plan of Care section and that is how/what the CCDA validator is built to follow. Thus, coded entries for future procedures and lab tests need to be in the Plan of Care section.
  - In order to facilitate the translation of SNOMED CT® codes to ICD-10-CM in administrative systems, developers are encouraged to reference the publicly available mapping that the National Library of Medicine provides. [see 77 FR 54220]
  - We provide the following OIDs to assist developers in the proper identification and exchange of health information coded to certain vocabulary standards.
    - ICD-10 Procedure Coding System OID: 2.16.840.1.113883.6.4
    - SNOMED CT® OID: 2.16.840.1.113883.6.96 [see also 80 FR 62612]
- Health IT Modules can present for certification to a more recent version of SNOMED CT®, U.S. Edition than the September 2015 Release per ONC's policy that permits certification to a more recent version of certain vocabulary standards. [see also 80 FR 62620]
- CPT codes are acceptable for the test procedure and test data. Please refer to the test procedure for more details.
- The C-CDA Cognitive Status Observation template has been deprecated in Release 2.1 and has been replaced with the Mental Status Observation template. Developers should use the Mental Status

Observation template for cognitive status and be aware that the C-CDA validator will issue an error if the deprecated Cognitive Status Observation template is used instead.

- In order to mitigate potential interoperability errors and inconsistent implementation of the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1, ONC assesses, approves, and incorporates corrections as part of required testing and certification to this criterion. [see FAQ #51] Certified health IT adoption and compliance with the following corrections are necessary because they implement updates to vocabularies, update rules for cardinality and conformance statements, and promote proper exchange of C-CDA documents. Consistent with FAQ 51, there is a 90-day delay from the time the CCG has been updated with the ONC-approved corrections to when compliance with the corrections will be required to pass testing (i.e., C-CDA 2.1 Validator). Similarly consistent with FAQ 51, there will be an 18-month delay before a finding of a correction's absence in certified health IT during surveillance would constitute a non-conformity under the Program.
  - March 2017 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 28, 2017; Surveillance compliance date is March 29, 2019]
  - April 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on July 31, 2018; Surveillance compliance date is November 2, 2019]
  - August 2018 Validator Update of C-CDA 2.1 Corrections [Effective for testing on December 20, 2018; Surveillance compliance date is March 21, 2020]

Paragraph (b)(6)(iii)(A)

Technical outcome – A user can set/enter the date and time period within which data would be used to create the export summaries.

Clarifications:

- A user must be able to express a start and end date range to meet this requirement. [see also 80 FR 62646]
- The request to enter back dated test data is to simulate previously entered tests so that certain portions of data sit inside a specific period of time.

Paragraph (b)(6)(iii)(B)

Technical outcome – A user can do each of the following for the date and time specified in provision (iii)(A):

(1) Create export summaries in real-time;

(2) Create export summaries based on a relative date and time (e.g., the first of every month at 1:00am); and

(3) Create export summaries based on a specific date and time (e.g., on 10/24/2015 at 1:00am).

Clarifications:

- A user would need to be able to: 1) create an export summary or export summaries in real-time (i.e., on demand); 2) configure technology to create such summaries based on a relative date and time (e.g., generate a set of export summaries from the prior month on the first of every month); and 3) configure technology to create such summaries based on a specific date and time (e.g., generate a set of export summaries with a date range between January 1, 2015 and March 31, 2015 on April 1, 2015 at 1:00AM EDT). We reiterate that a Health IT Module will need to support the user's ability to select and configure those dates and times. [see also 80 FR 62646]

Paragraph (b)(6)(iv)

Technical outcome – A user can set the storage location to which the export summary or export summaries are intended to be saved.

Clarifications:

- A Health IT Module must, at a minimum, permit a user to select a local or network storage location. We have intentionally left the specific transport method (e.g., sending to a Direct email address) or further product integration (e.g., routing the export to a web service or integration engine) to the discretion of the health IT developer and its customers. [see 80 FR 62646]

Content last reviewed on June 22, 2020